Catheter Tensioning Device

Instructions for Use

REF 351201

Manufacturer

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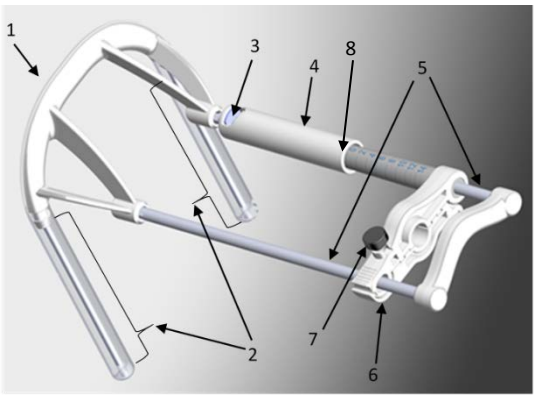
Indications for Use

The Catheter Tensioning Device (CTD) is intended for maintaining a known tension on a transurethral balloon catheter.

Device Description

The Catheter Tensioning Device (CTD) is a sterile single use device. It is attached in the pubis region of the patient and allows the physician or nurse to apply a known tension on a transurethral catheter up to 24 Fr. The device allows the user to adjust and maintain catheter tension for an extended duration. It is made of metallic and non-metallic components, allowing it to be formed to patient specific anatomy to reduce discomfort. The CTD clamps onto an adhesive flag applied by the user, allowing the transurethral catheter lumens to remain patent while under tension. No component of this device is inserted into the body.



Tape Applicator

Number	Description
1	Base
2	Malleable section of Base
3	Lock
4	Spring Tensioner
5	Rod
6	Clamp
7	Clamp Knob
8	Scale: 0 – 15 hectogram-force, e.g. 10 = 1000gf Scale Tolerance: ±200gf

Contraindication

None

Warnings

- Intended for single use only. Do not reuse. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, or illness.
- Do not re-sterilize. The sterility of the single use device is not guaranteed following re-sterilization because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Re-sterilization may compromise the structural integrity, essential material and/or design characteristics and may lead to an unpredictable loss of functionality and/or device failure.

Precautions

- Do not use the Catheter Tensioning Device where loss of placement on pubis region could occur, such as with a mobile patient
- Observe universal blood and body fluid precautions and infection control procedures, during the Catheter Tensioning Device application and removal from the patient.
- Minimize transurethral catheter manipulation during application and removal of the Catheter Tensioning Device.
- Remove oil and lubrication from area where adhesive flag will be placed on transurethral catheter.
- Securely engage rods into base of the Catheter Tensioning Device to prevent loss of transurethral catheter tensioning.
- Securely clamp onto adhesive flag to prevent loss of transurethral catheter tensioning.
- Ensure transurethral catheter is not pinched in the clamping door to prevent occlusion of the catheter lumens.
- Do not use a transurethral catheter greater than 24 Fr with the Catheter Tensioning Device.
- Ensure additional tension is not applied after the maximum tension has set per the scale on the device.
- For maximum patient comfort, always conform the malleable section of the Catheter Tensioning Device to properly seat against the patient anatomy.
- The Catheter Tensioning Device should be monitored and replaced in accordance with facility protocol.
- Use aseptic technique for application of the Catheter Tensioning Device.
- Apply a minimum of 300g of tension on the transurethral catheter to ensure stability of the Catheter Tensioning Device on the patient.
- Ensure any tubing attached to catheter is relaxed and does not inadvertently apply excess tension.
- Inspect Catheter Tensioning Device packaging to ensure integrity. Do not use if package is damaged or open.

Special Storage and Handling Instructions

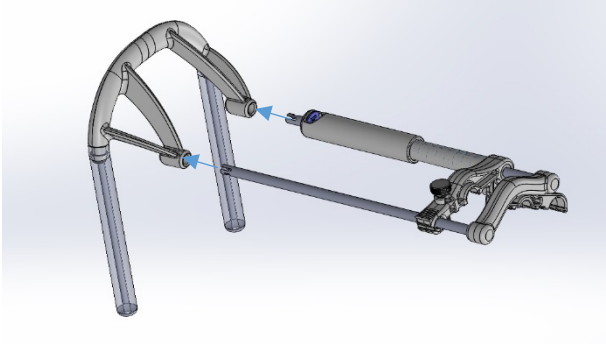
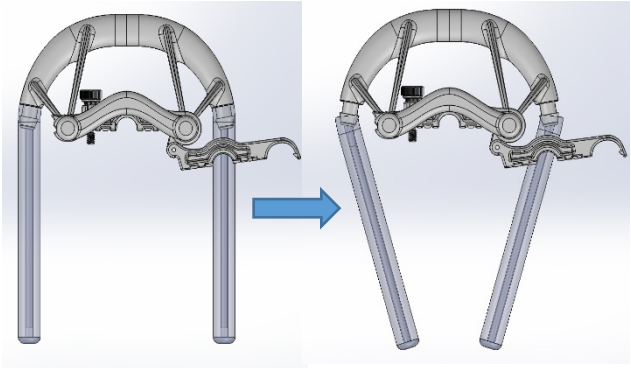
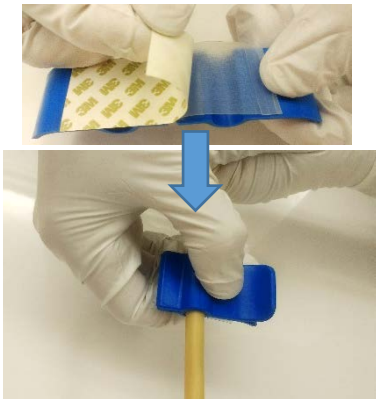
Do not store product above 131°F (55°C) or below -14°F (-10°C).

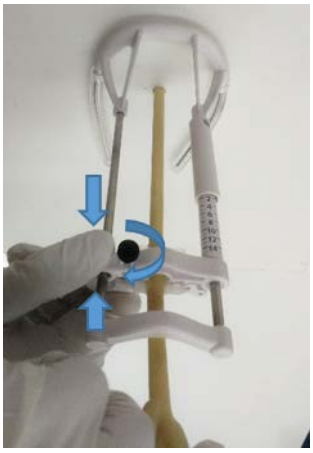
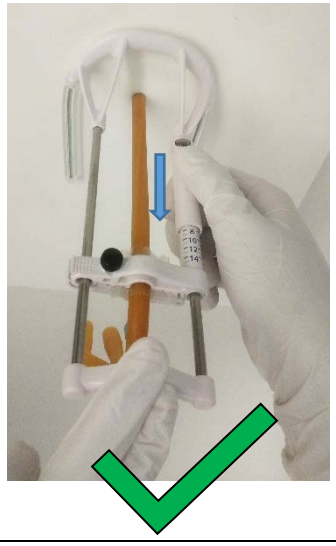
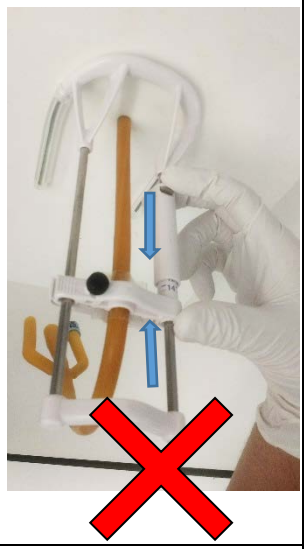
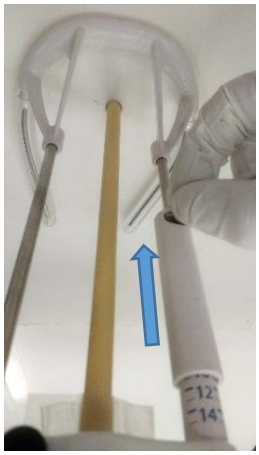
Do not use product above 95°F (35°C) or below 50°F (10°C).

How Supplied

The Catheter Tensioning Device is supplied sterile.

Instructions for Use

Catheter Tensioning Device Application	
Remove both components of Catheter Tensioning Device from the packaging card. Slide the Rod portion firmly into the Base portion oriented as shown. Confirm Rods are locked into Base by gently attempting to remove.	
Place Catheter Tensioning Device on pubis region of patient and bend the malleable section of the Catheter Tensioning Device to conform to the patient anatomy.	
Upon transurethral catheter insertion and balloon inflation, thoroughly dry area on Foley catheter where the adhesive flag will be placed. Remove backing from tape on Tape Applicator while holding down the tab. Close Tape Applicator onto catheter where tape is to be placed (ensuring location is between tip of penis and clamp). Remove Applicator leaving behind a tape flag.	

Apply a small amount of tension to the catheter and close Clamp on flag. Tighten the Clamp Knob. Precaution: Ensure the catheter is seated in the Inner Diameter of clamp and the flag is secure in the grasping feature.	
Apply desired catheter tension by sliding the Spring Tensioner away from the pubis. Precaution: Apply tension using Spring Tensioner. Do not anchor thumb against Clamp when adjusting tension.	 
If necessary, release the lock by pinching the lock towards the pubis to release tension. Tension can be reapplied by sliding the spring tensioner away from the pubis Note: Tension may be readjusted as desired in the Operating Theatre or Recovery Ward.	

Catheter Tensioning Device Removal		
Physician	To remove catheter from Catheter Tensioning Device, release all tension, loosen Clamp Knob and open Clamp	

Graphic Symbols Contained in Device Labeling

	Batch Code		Do Not Reuse		Keep Dry
	Catalog Number		Use By		Manufacturer
	Sterilized Using Ethylene Oxide		Consult Instructions for Use		Do Not Use if Package Is Damaged or Opened
	Temperature Limit		Humidity Limit		Keep Away from Sunlight
	Do not reseterilize		Authorized EU Representative		